



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/366,458	08/03/1999	WILLIAM J. DREYER	CIT1150-1	3096

7590

11/05/2002

GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO, CA 921212189

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/05/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/366,458

Applicant(s)

DREYER, WILLIAM J.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 50-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 50-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 29, 2002 is acknowledged. Claims 1 and 5 were amended and 58-64 were added.

Claims 1-10 and 50-64 are pending in the application and examined on the merits.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim Rejections Withdrawn:

3. The rejections of claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn upon further consideration.

Claim Rejections Maintained:

4. The rejection of claims 1-10, and 50-57 under 35 U.S.C. 103(a) as being unpatentable over Nef and Nef, PNAS, Vol. 94, pages 4766-4771, April 1997, or Drutel et al., Receptors and Channels, Vol. 3, pages 33-40, 1995, or Vanderhaeghen et al., Biochemical and Biophysical Research Communications, Vol. 237, pages 283-287, 1997, or Mombaerts et al., Cell, Vol. 87, pages 675-686, November 15, 1996, in view of Janeway and Travers, Immunobiology, pages 2:20-2:30, 1997, or Stites et al., Basic and Clinical Immunology pages 291-293, 1987, or Schlossman et al., Purification of B Lymphocytes, pages 313-315, 1973, or Seed et al., PNAS,

Art Unit: 1642

Vol. 84, pages 3365-3369, May 1987, or Wysocki et al., PNAS, Vol. 75, No. 6, pages 2844-2848, June 1978, or Aruffo et al., PNAS, Vol. 84, pages 8573-8577, December, 1987, or Heller et al., PNAS USA, Vol. 94, pages 2150-2155, March 1997, or Foote, US Patent 5,661,628, August 26, 1997 is maintained for the reasons of record. This rejection is also applied to new claims 58-64.

Applicants arguments have been carefully considered but are unpersuasive. Claims 1-10 and 50-64 are broadly drawn to methods for obtaining compositions of cells that are substantially enriched with cells of a specific progenitor cell type or a specific cell type. The term substantially enriched is broadly interpreted to mean that the concentration of cells relative to other cells is altered from what is found in nature. Applicants arguments that there is no motivation to combine the cited references is unpersuasive because it is well known in the art that if a cell protein is discovered to be preferentially located on one cell type that this cell protein may be used as a basis for a selection method. Thus, for example, the teaching of Drutel that OL1 is expressed in heart cells during development provides the basis for a cell selection method (see abstract). The claims are drawn to methods of sorting cells, to obtain an enriched cell population. Such methods are well established in the art as set forth above, regardless of what type of cell is being sorted. Discovery of a previously unknown property of a cell does not make the enrichment of that cell patentable, when the methods of enrichment, the cell itself, and its general function were previously known. Therefore, the rejection is maintained.

As set forth in the previous Office Action, Nef and Nef teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic

Art Unit: 1642

function. Nef and Nef further teach DNA analysis of the olfactory positive cells, including Southern Blot analysis. (see for example, abstract). Drutel et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells function in olfactory development, sperm chemotaxis, and odor and taste recognition (see for example, abstract and page 33, first paragraph). Drutel et al. further teach DNA analysis of the olfactory positive cells. Vanderhaeghen et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory function Vanderhaeghen et al. further teach DNA analysis of the olfactory positive cells. (see for example, abstract) Mombaerts et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic function. Mombaerts et al. further teach DNA analysis of the olfactory positive cells (see for example, abstract). Thus olfactory cells and their functions are known in the art.

Nef and Nef, Drutel et al., Vanderhaeghen et al., or Mombaerts et al. fail to teach sorting and enrichment of cells which express olfactory (serpentine) receptors, cell sorting using at least one additional marker, or at least one binding assay, and microchip analysis. The sorting an enrichment of cells which are known to express a receptor, cell sorting using at least one additional marker, or at least one binding assay, and microchip analysis, are well known in the art.

Methods of cell sorting, purification and selection based on specific receptor expression are well established in the art. For example, Janeway and Travers, teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, protein affinity purification, and FACS (including multiple markers, immobilized binding agents, multiple binding agents, monoclonal and polyclonal antibodies, as well as DNA analysis) (see pages 2:20-2:30). Stites et

Art Unit: 1642

al. teaches methods of selecting specific cells and purifying those cells using FACS (including monoclonal and polyclonal antibodies and DNA analysis) (see pages 23291-291). Schlossman et al. teaches methods of sorting and purifying B-lymphocytes using polyclonal antibodies (see page 313). Seed et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot and including the cell adhesion molecule CD2. Wysocki et al. teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, and protein affinity purification (including multiple markers, immobilized binding agents, and polyclonal antibodies) Aruffo et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot, and including the cell adhesion molecule CD2. Heller et al., teaches DNA analysis of selected cells using micro array design. Foote, US Patent 5,661,628 teaches an example a microchip used for DNA analysis and methods of using such. (see for abstract and entire document). Thus the specific methods of sorting and analyzing cells were known in the art, as set forth and exemplified above.

Therefore, it would have been prima facie obvious to one of skill in the art to sort and analyze the olfactory (serpentine) marker expressing cells to obtain an enriched composition, using serpentine receptors, with or without another cell marker, and one would have been motivated to do so to test for olfactory function, sperm chemotaxis, or neurological function, and to use the cells to study these functions and provided treatment which correspond to failures of these systems, as set forth above.

Art Unit: 1642

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
November 4, 2002

B
ANTHONY A. CAPUTA
PATENT EXAMINER
NOV 14 2002